

REMARKS**Amendments to the Specification**

The amendments to the specification on pages 7 and 12 of the application are presented to correct obvious typographical errors relating to the use of particular reference numerals in relation to FIGS. 3 and 4. No new matter has been added with regard to these amendments. Entry of these corrections is cordially requested.

Status of the Claims

Claims 1-20 are pending in the present application. Amendments to claims 13 and 14 are requested. New claim 21 is presented for entry into the present application. Reconsideration of claims 1-20 and examination of claim 21 are cordially requested.

Amendments to the Claims

Claim 10 is amended to include the phrase, “the first flexible bellows being sequentially connected to the second flexible bellows.” Support for this amendment is provided by the bellows arrangement explicitly shown in FIG. 3. Claim 13 is amended to depend from claim 12 instead of claim 11 to provide appropriate antecedent basis. Claim 14 is amended to depend from claim 10 instead of claim 13. Entry of these amendments is cordially requested.

Novelty

Claims 1-9 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by Saens-Arrollo (U.S. Patent No. 5,810,761). Claims 1-9, however, are novel because Saens-Arrollo fails to teach a biasing element in a hydrocephalus valve that (i) has an adjustable resistance; and/or (ii) allows fluid release at a rate proportional to an average pressure difference over time.

Independent claim 1 is drawn to a self adjusting hydrocephalus valve for regulating cerebrospinal fluid. The valve includes a housing enclosing a chamber, and inlet and outlet ports for accommodating passage of fluid into and out of the chamber, respectively. The claim also recites a valve mechanism having a valve seat, a blocking member configured to seat in the valve seat, and a biasing element for exerting a biasing force against the blocking member to

selectively maintain the blocking element against the valve seat. In particular, the biasing element “has an adjustable resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.”

Saens-Arrollo provides no teaching or suggestion of a biasing element meeting the recitation of claim 1. Saens-Arrollo reveals a pressure control device, integrated in a pressure control valve, for draining cephalorachidian liquid. The patent specifically states that the resistance of the valve “is mainly determined by the [pressure control] device . . . which is set to open and close within the specifically preset pressure range” (see Saens-Arrollo, column 2, lines 12-15, emphasis added). That is, the resistance of the pressure control device is predefined by the device’s configuration. There is no mention of a biasing element that has an *adjustable* resistance.

Furthermore, Saens-Arrollo fails to provide any teaching or suggestion of a biasing element “to allow fluid release at a rate which is proportional to an average pressure difference over time.” Saens-Arrollo only notes that the valve “stops the flow when the entrance fluid pressure is lower than the mechanical pressure applying part (C)” (see id., column 3, lines 28-31); there is no further disclosure regarding the fluid release characteristics. As well, the fluid release rate characteristic mentioned in claim 1 is not inherent in the device of Saens-Arrollo. With particular reference to FIGS. 2 and 3 in the reference, the pressure control bellows C has perforations K through which fluid entering the valve must pass through when the bellows allows fluid flow. Thus, the pressure inside in the pressure control bellows equilibrates quickly with the pressure outside the bellows. With this feature, and the failure of Saens-Arrollo to discuss other necessary configurations of other parts of the bellows , the pressure control bellows cannot control fluid release at a rate proportional to an average pressure difference over time.

Accordingly, Saens-Arrollo provides no teaching or suggestion of a biasing element having “an adjustable resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.” For these reasons, among other, claim 1 not anticipated by the reference. Claims 2-9 depend from claim 1, and are not anticipated for substantially the same reasons, among others. In particular, claims 6 and 7 are distinguished from Saens-Arrollo since the reference does not teach a valve having an end plate connected to a support member

(claim 6), or a support member that includes apertures permitting fluid flow therethrough (claim 7).

Nonobviousness

Claims 10-20 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Saens-Arrollo. Since claims 10-20 depend from claim 1, and the Examiner provides no references to augment the teachings of Saens-Arrollo, the claims are nonobvious because, as stated earlier, Saens-Arrollo does not teach or suggest a biasing element having “an adjustable resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.” The presence of two sequentially connected flexible bellows in claims 10-20 is not mere duplication of the working parts of a device found in the prior art, as stated by the Examiner, since Saens-Arrollo does not teach or suggest the biasing element recited in the claims.

For this reason, among others, claims 10-20 are patentable. As well, claims 12 and 13 are patentable for the independent reasons that Saens-Arrollo does not teach a support member between two bellows (claim 12), and/or a support member including apertures permitting fluid flow therethrough (claim 13). Claim 14 is also patentable for the independent reason that Saens-Arrollo provides no teaching or suggestion of a first and second bellows forming a closed fluidic system. As shown in FIGS 2 and 3 of Saens-Arrollo, the bellows structure C has a number of apertures K, L that allow fluid flow therethrough (also see earlier discussion). The bellows structure C is in no way a closed fluidic system. Claim 18 is also patentable for the independent reason that Saens-Arrollo does not teach a biasing element at least partially filled with an inert gas. In contradiction with the Office Action statement that the bellows in Saens-Arrollo contains normal atmospheric inert air therein during normal circumstances, the reference clearly shows that the volume within the pressure control bellows C is filled with cephalorachidian liquid during operation (see Saens-Arrollo, FIG. 2 and column 3, lines 35-38). Indeed, if the bellows is filled with an inert gas, fluid could not flow through the valve since the inside of the bellows in a portion of the unique passageway for fluid flow.

New Claim 21

New claim 21 is presented for entry into the present application. Support for the claim is found in FIG. 3 of the present application and the corresponding description at page 7, lines 1-16. Claim 21 is clearly patentable over Saens-Arrollo since the reference does not teach or suggest a biasing element accommodating passage of fluid from the inlet port to the chamber without passage through the biasing element (see Saens-Arrollo, FIGS. 2 and 3).

CONCLUSION

In view of the remarks above, Applicant submits that claims 1-21 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Dated: November 11, 2005

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